OCT 2 8 2004

K042275

Summary of Safety and Effectiveness

Submitter Information	Company:	VISTAKON® Division of Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Suite 100 Jacksonville, FL 32256
	Contact Person:	Annette M. Hillring President Hillring & Associates, Inc.
	Telephone: FAX:	813-269-8246 813-908-8706
	Date Prepared:	August 20, 2004
Identification of the Device	Common Name:	Soft Contact Lens
	Device Name:	VISTAKON® (senofilcon A) Contact Lens
	Classification Name:	Soft Hydrophilic Contact Lens, Daily Wear
	Device Classification:	Class II, 21 CFR 886.5925 (b) (1).
Predicate Device	The predicate device was selected to address both intended use (daily wear) and material type (FDA Group I; low water, nonionic polymer): • Focus® NIGHT AND DAY™ (lotrafilcon A), FDA Group I.	

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Summary of Safety and Effectiveness, Continued

Description of Device

- The VISTAKON® (senofilcon A) Contact Lens Clear and Visibility Tint with UV Blocker is available as a spherical lens, a multifocal lens, a toric lens and a multifocal-toric lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (senofilcon A) Contact Lens may be tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 – 315nm and less than 10% in the UVA range of 316 – 380nm.
- The VISTAKON® (senofilcon A) Contact Lens is a hemispherical or hemitoric shell.
- The lens is supplied in a sterile state, packaged in a buffered saline solution with 0.005% methyl ether cellulose.
- The composition of the lens is 62% senofilcon A and 38% water by weight when hydrated and stored in the buffered saline solution.

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Summary of Safety and Effectiveness, Continued

Indications for Use

Lens Design	Indication
Spherical	The VISTAKON® (senofilcon A) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less.
Multifocal	The VISTAKON® (senofilcon A) Multifocal Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less
Toric	The VISTAKON® (senofilcon A) Toric Contact Lens is indicated for daily wear for the correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism or less.
Multifocal Toric	The VISTAKON® (senofilcon A) Multifocal-Toric Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.

- VISTAKON® (senofilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

- Eye care practitioners may prescribe the lens for single-use disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement, the lens may be disinfected using a chemical disinfection system only.

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Summary of Safety and Effectiveness, Continued

Technological Characteristics

The characteristics of the VISTAKON® (senofilcon A) Contact Lens are compared to the characteristics of the predicate device, Focus® NIGHT & DAY™ (lotrafilcon A) Contact Lens, in the following tables.

Material Comparison		
	Focus® NIGHT AND DAY™ (lotrafilcon A) Contact Lens	VISTAKON® (senofilcon A) Contact Lens
Material	lotrafilcon A	senofilcon A
Type	Group I	Group I

Parameter Comparison				
	Focus® NIGHT AND DAY™ (lotrafilcon A) Contact Lens		VISTAKON® (senofilcon A) Contact Lens	
	Measured	Labeled	Measured	Labeled
Water Content, %	23	24	38	38
Refractive Index @ 20°C	1.43	1.43	1.42	1.42
Dk*, edge corrected	141	140	107	103
Dk*, non-edge corrected	168	NA	126	122
Base Curve, mm	8.47	8.4	8.81	8.8
Diameter, mm	13.80	13.8	14.62	14.6
Power, D	-1.11	-1.00	-0.35	-0.50

*Dk units: $10^{-11}(cm^2/sec)(ml\ O_2/ml \times mmHg)$

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Summary of Safety and Effectiveness, Continued

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All non-clinical toxicology tests were conducted in accordance with the GLP regulation (21 CFR Part 56). All other testing was conducted according to valid scientific protocols.

The results of the non-clinical testing on the VISTAKON® (senofilcon A) Contact Lens demonstrate that:

- the lens material and extracts are not toxic and not irritating, and
- lens physical and material properties are consistent with currently marketed lenses.

Clinical Testing

A three-month clinical study was completed to evaluate the safety and efficacy of the VISTAKON® (senofilcon A) Contact Lens when worn by myopic patients on a daily wear basis. The clinical study was conducted in accordance with FDA's 1994 Guidance Document for Daily Wear Contact Lenses.

The study evaluated at least 50 patients with a 2:1 ratio of subject device to predicate device for three (3) months. Parameters measured included adverse reactions, keratometry changes, reasons for discontinuations, and the number of reasons for unscheduled lens replacements.

Clinical evaluation demonstrated similar overall performance in the clinically relevant areas of vision, health, comfort and fit as compared to concurrent controls when used under daily wear conditions.

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Summary of Safety and Effectiveness, Continued

Conclusions Drawn from Studies

Validity of Scientific Data	Toxicology studies were conducted under the Good Laboratory Practices Regulations by a contract laboratory. Microbiology, chemistry, shelf-life stability, and leachability studies were conducted by VISTAKON® laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7
Substantial Equivalence	Information presented in this Premarket Notification establishes that the VISTAKON® (senofilcon A) Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.
Risk and Benefits	The risks of the subject device as the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2004

Vistakon
c/o Ms. Annette M. Hillring
President, Hillring & Associates, Inc.
3012 St. Charles Drive
Tampa, FL 33618

Re: K042275
Trade/Device Name: Vistakon^{R} (senofilcon A) Contact Lens for Daily Wear
(Clear and Visibility Tint with UV Blocker)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL; MVN
Dated: August 20, 2004
Received: August 23, 2004

Dear Ms. Hillring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: VISTAKON® (senofilcon A) Contact Lens Clear and Visibility Tint, with UV blocker

Indications for Use:

The VISTAKON® (senofilcon A) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON® (senofilcon A) Multifocal Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75 D of astigmatism or less.

The VISTAKON® (senofilcon A) Toric Contact Lens is indicated for daily wear for the correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D of astigmatism or less.

The VISTAKON® (senofilcon A) Multifocal-Toric Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00 D of astigmatism or less.

VISTAKON® (senofilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K042275